

## Subpart F—Therapeutic Devices

### § 878.5070 Air-handling apparatus for a surgical operating room.

(a) *Identification.* Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) *Classification.* Class II.

### § 878.5350 Needle-type epilator.

(a) *Identification.* A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

### § 878.5360 Tweezer-type epilator.

(a) *Identification.* The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[63 FR 57060, Oct. 26, 1998]

### § 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device intended to surround hermetically a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to

aid healing of chronic skin ulcers or bed sores.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

### § 878.5900 Nonpneumatic tourniquet.

(a) *Identification.* A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

### § 878.5910 Pneumatic tourniquet.

(a) *Identification.* A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

## PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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- 880.2200 Liquid crystal forehead temperature strip.
- 880.2400 Bed-patient monitor.
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- 880.2720 Patient scale.
- 880.2740 Surgical sponge scale.
- 880.2800 Sterilization process indicator.
- 880.2900 Clinical color change thermometer.
- 880.2910 Clinical electronic thermometer.
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- 880.5025 I.V. container.
- 880.5045 Medical recirculating air cleaner.
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- 880.5100 AC-powered adjustable hospital bed.
- 880.5110 Hydraulic adjustable hospital bed.
- 880.5120 Manual adjustable hospital bed.
- 880.5130 Infant radiant warmer.
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- 880.5150 Nonpowered flotation therapy mattress.
- 880.5160 Therapeutic medical binder.
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- 880.5240 Medical adhesive tape and adhesive bandage.
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- 880.5300 Medical absorbent fiber.
- 880.5400 Neonatal incubator.
- 880.5410 Neonatal transport incubator.
- 880.5420 Pressure infusor for an I.V. bag.
- 880.5430 Nonelectrically powered fluid injector.
- 880.5440 Intravascular administration set.
- 880.5450 Patient care reverse isolation chamber.
- 880.5475 Jet lavage.
- 880.5500 AC-powered patient lift.
- 880.5510 Non-AC-powered patient lift.
- 880.5550 Alternating pressure air flotation mattress.
- 880.5560 Temperature regulated water mattress.
- 880.5570 Hypodermic single lumen needle.
- 880.5580 Acupuncture needle.
- 880.5630 Nipple shield.
- 880.5640 Lamb feeding nipple.
- 880.5680 Pediatric position holder.
- 880.5700 Neonatal phototherapy unit.
- 880.5725 Infusion pump.

- 880.5740 Suction snakebite kit.
- 880.5760 Chemical cold pack snakebite kit.
- 880.5780 Medical support stocking.
- 880.5820 Therapeutic scrotal support.
- 880.5860 Piston syringe.
- 880.5950 Umbilical occlusion device.
- 880.5960 Lice removal kit.
- 880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.
- 880.5970 Percutaneous, implanted, long-term intravascular catheter.

**Subpart G—General Hospital and Personal Use Miscellaneous Devices**

- 880.6025 Absorbent tipped applicator.
- 880.6050 Ice bag.
- 880.6060 Medical disposable bedding.
- 880.6070 Bed board.
- 880.6080 Cardiopulmonary resuscitation board.
- 880.6085 Hot/cold water bottle.
- 880.6100 Ethylene oxide gas aerator cabinet.
- 880.6140 Medical chair and table.
- 880.6150 Ultrasonic cleaner for medical instruments.
- 880.6175 [Reserved]
- 880.6185 Cast cover.
- 880.6190 Mattress cover for medical purposes.
- 880.6200 Ring cutter.
- 880.6230 Tongue depressor.
- 880.6250 Patient examination glove.
- 880.6265 Examination gown.
- 880.6280 Medical insole.
- 880.6300 Implantable radiofrequency transponder system for patient identification and health information.
- 880.6320 AC-powered medical examination light.
- 880.6350 Battery-powered medical examination light.
- 880.6375 Patient lubricant.
- 880.6430 Liquid medication dispenser.
- 880.6450 Skin pressure protectors.
- 880.6500 Medical ultraviolet air purifier.
- 880.6710 Medical ultraviolet water purifier.
- 880.6730 Body waste receptacle.
- 880.6740 Vacuum-powered body fluid suction apparatus.
- 880.6760 Protective restraint.
- 880.6775 Powered patient transfer device.
- 880.6785 Manual patient transfer device.
- 880.6800 Washers for body waste receptacles.
- 880.6820 Medical disposable scissors.
- 880.6850 Sterilization wrap.
- 880.6860 Ethylene oxide gas sterilizer.
- 880.6870 Dry-heat sterilizer.
- 880.6880 Steam sterilizer.
- 880.6885 Liquid chemical sterilants/high level disinfectants.
- 880.6890 General purpose disinfectants.
- 880.6900 Hand-carried stretcher.
- 880.6910 Wheeled stretcher.
- 880.6920 Syringe needle introducer.
- 880.6960 Irrigating syringe.
- 880.6970 Liquid crystal vein locator.

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880.6980 Vein stabilizer.  
880.6990 Infusion stand.  
880.6991 Medical washer.  
880.6992 Medical washer-disinfector.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 69682, Oct. 21, 1980, unless otherwise noted.

### Subpart A—General Provisions

#### § 880.1 Scope.

(a) This part sets forth the classification of general hospital and personal use devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a general hospital and personal use device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17738, May 11, 1987, as amended at 69 FR 71704, Dec. 8, 2004]

#### § 880.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving

an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a 'new' devices defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of